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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,344	10/15/2003	Ivan Osorio	011738.00149	7817

70467 7590 08/02/2010

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EXAMINER	
RAJAN, KAI	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
08/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,344	OSORIO ET AL.	
	Examiner	Art Unit	
	Kai Rajan	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11,12 and 14-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,12 and 14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/25/2009*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application.

6)☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the response and amendment filed April 7, 2010. Furthermore, the case has been transferred to Examiner Kai Rajan for further prosecution.

Allowable Subject Matter

The indicated allowability of claims 12 and 14 – 23 is withdrawn in view of the rejections presented below.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection. The finality of the previous action has been withdrawn, and a new non-final rejection is presented below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15, 16, 22 and 23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In particular, the claims are drawn to a process, and process claims must: 1) be tied to a particular machine or apparatus performing the essential steps of the method; or 2) transform underlying subject matter such as an article to a different state or thing. In this case, the claims fail to recite the machine performing the process steps,

such as a processor. As such, numerous steps of the method are interpreted as mental steps. Furthermore, the method of receiving input, administering therapy, and receiving indications does not result in a transformation of an article.

Claims 12, 14, and 17 are rejected under 35 U.S.C. 101 because the broadest reasonable interpretation of "computer readable medium" includes carrier waves, which are not patentable. The Examiner suggests claiming "a *non-transitory* computer readable medium" to overcome this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 15, 21, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, it is unclear in the step of "receiving a first indication [at the at least one processor] whether the treatment therapy is acceptable" and "receiving a second indication [at the at least one processor]" whether the processor generates the first and second indications, or whether the processor merely receives the indication manually input by a user or communicated from a remote location.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 8, 11, 12, and 14 - 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al. U.S. Patent No. 5,713,923, cited by Applicant.

1. (Currently Amended) A method for performing trial screening with a medical device system, the medical device system providing treatment to a patient with a nervous system disorder, the method comprising:

(a) receiving a first input into at least one processor relating to a location of treatment therapy delivery (Column 8 lines 29 – 54, Column 9 lines 40 – 67, column 10 lines 1 – 34, table II sensors receive data from specific brain sites which is fed into a microprocessor with associated brain coordinates for analysis);

(b) receiving a second input into the at least one processor about a set of therapy parameters that is associated with a treatment therapy (Column 8 lines 36 – 54, column 9 lines 5 – 14 levels and ranges programmed by clinicians regarding sensed parameters as thresholds for changing or providing therapy);

(c) administering a treatment therapy by the at least one processor in accordance with the first and second inputs (Column 3 lines 13 – 35, column 6 lines 15 – 26 microprocessor controls drug delivery and electrical stimulation in response to measured sensor parameters at specific brain locations and thresholds or ranges set by a clinican); and

(d) receiving a first indication at the at least one processor whether the treatment therapy is acceptable to the patient and a second indication at the at least one processor whether to utilize

the first and second inputs, wherein the second indication is determined by evaluating a criterion, wherein the criterion is selected from a group consisting of a detection frequency of the neurological event, a duration of the neurological event, an intensity of the neurological event, and an electrographic spread of the neurological event (Column 4 lines 66, 67, column 5 lines 1 - 25, column 6 lines 15 - 25, column 8 lines 21 - 54, column 9 lines 5 – 35, column 10 lines 1 – 60 stimulation and drug delivery are controlled in a closed loop system by the microprocessor. Stimulation and drug dosages are modified depending on seizure activity of the patient as detected by the sensors. Therefore, when an amount and frequency of seizure activity is detected that exceeds preset limits, therapy is determined unacceptable and is modified until sensed parameters are within acceptable limits).

2. (Previously Presented) The method of claim 1, further comprising:

(e) if the first indication indicates that the treatment therapy is acceptable and if the second indication indicates that the first and second inputs are to be used, applying the treatment therapy at a future point in time (Column 4 lines 66, 67, column 5 lines 1 - 25, column 6 lines 15 - 25, column 8 lines 21 - 54, column 9 lines 5 – 35 therapy is delivered after the evaluation of sensed parameters and preset limits, which is a future point in time).

3. (Original) The method of claim 1, wherein the nervous system disorder is selected from the group consisting of a disorder of a central nervous system, a disorder of a peripheral nervous system, a mental health disorder, and a psychiatric disorder (Column 3 lines 13 – 22 neurological disorder such as epilepsy is treated).

4. (Original) The method of claim 3, wherein the nervous system disorder is selected from the group consisting of epilepsy, Parkinson's disease, essential tremor, dystonia, multiple sclerosis (MS), anxiety, a mood disorder, a sleep disorder, obesity, and anorexia (Column 3 lines 13 – 22 neurological disorder such as epilepsy is treated).

5. (Original) The method of claim 1, wherein the treatment therapy is selected from the group consisting of electrical stimulation, magnetic stimulation, drug infusion, and brain temperature control (Column 3 lines 13 – 35, column 6 lines 15 – 26 microprocessor controls drug delivery and electrical stimulation).

6. (Original) The method of claim 1, wherein the treatment therapy is provided to a location of a body selected from the group consisting of a brain, a vagal nerve, a spinal cord, and a peripheral nerve (Column 8 lines 29 – 54, Column 9 lines 40 – 67, column 10 lines 1 – 34, table II specific brain sites are monitored and treated).

7. (Original) The method of claim 1, wherein the medical device system is selected from the group consisting of an external system, a hybrid system, and an implanted system (Column 3 lines 13 – 38 implanted system).

8. (Previously Presented) The method of claim 2, further comprising:

(f) in response to step (e), if the treatment therapy is not successful, repeating steps (a)-(d) (Column 4 lines 66, 67, column 5 lines 1 - 25, column 6 lines 15 - 25, column 8 lines 21 - 54, column 9 lines 5 – 35 stimulation and drug delivery are controlled in a closed loop system, where closed loop systems continuously modify an output based on feedback received from sensors. Treatment is continuously modified until sensor parameters are within acceptable limits).

11. (Previously Presented) The method of claim 1, wherein the evaluating in (d) comprises:

(i) obtaining treatment data during the trial screening session, wherein the treatment therapy is applied (Column 8 lines 29 – 54, Column 9 lines 40 – 67, column 10 lines 1 – 60, table II sensors receive data from specific brain sites before, during, and after treatment);

(ii) obtaining comparison data during a neurological event screening session, wherein the treatment therapy is not applied (Column 8 lines 29 – 54, Column 9 lines 40 – 67, column 10 lines 1 – 60, table II sensors receive data from specific brain sites before, during, and after treatment), and

wherein the comparison data correspond to the treatment data;

(iii) deleting a portion of the comparison data corresponding to a blanking interval of the treatment therapy; and (iv) calculating a difference between the treatment data and the comparison data in order to determine the efficacy of the treatment therapy (Column 8 lines 29 – 54, Column 9 lines 40 – 67, column 10 lines 1 – 60 efficacy of treatment therapy determined based on collected data over time regarding seizure activity compared to previous data to modify

therapy in a closed loop system and determine the most effective therapy schedule, dosing, and stimulation/drug combination).

12. (Original) A computer-readable medium having computer-executable instructions for performing the steps recited in claim 1 (Column 3 lines 13 – 35, column 6 lines 15 – 26 method is implemented on a processor and computerized system).

Claims 14 – 23 are rejected on substantially the same basis as claims 1 – 8, 11, and 12 above, by Ward et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is (571)272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kai Rajan/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769

July 31, 2010